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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,158	12/30/1999	Thomas J. Gardella	0609.4780001	6018
26111	7590	11/22/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/475,158

### Applicant(s)

GARDELLA ET AL.

### Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11 and 14-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-35 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6, 10, 11, 37, 41-43, and 46 is/are rejected.
- 7) ☒ Claim(s) 7-9,14,44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/07/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Amendments, and/or Claims Status of Application**

Applicants' amendment filed on September 7, 2004 has been entered in full. Claims 1, 7, 8, 41, and 42 have been amended. Claims 43-46 have been added. Claims 1, 2, 4-11, and 14-46 are pending. Claims 1, 2, 4-11, 14, 37, and 41-46 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Withdrawn Rejections and/or Objections**

The objections to the disclosure and Abstract have been withdrawn in view of Applicants' amendment to the specification and Abstract.

The rejection of claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Caulfield et al. (Endocrinology, 127: 83-87, 1990), as set forth in Paper No. 04302004 (May 4, 2004), has been withdrawn in view of Applicants' amendment to the claim 1 and cancellation of claim 3.

The rejection of claims 7-9 under 35 U.S.C. 112, first paragraph for written description, as set forth in Paper No. 04302004 (May 4, 2004), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 7-9 and 14 under 35 U.S.C. 112, first paragraph for scope of enablement, as set forth in Paper No. 04302004 (May 4, 2004), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 4, 7-11, and 14 under 35 U.S.C. §112, second paragraph, as set forth in Paper No. 04302004 (May 4, 2004), has been withdrawn in view of Applicants' amendment to the claims.

### **Drawings**

The drawings submitted on September 7, 2004 are accepted by the Examiner.

### **Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Scope of Enablement)**

The rejection of claims 1, 2, 4-6, 10, 11, 37, 41, 42, under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (Scope Enablement), as set forth in the previous office actions, is maintained. New claims 43 and 46 are also rejected under 35 U. S. C. § 112, 1<sup>st</sup> paragraph on the same basis.

It is noted that the amended claims are narrower in the scope of invention. However, it

is unreasonably broad.

At the bottom of page 12 of Applicants' response, Applicants, citing case law, argue that Applicants are not required to provide experimental examples of each and every polypeptide that would fall under the scope of the claims. The Examiner agrees. However, the specification is required to provide sufficient support to enable the full scope of invention. It is not the case here.

From the bottom of page 12 to top of page 13 of Applicants' response, Applicants argue that Applicants have amended the claims to recite linkers that are composed of either greater than 1 repeats of the same amino acid molecule, or 1 to 9 repeats of an aliphatic diamine molecule.

Applicants argument has been fully considered, but is not deemed to be persuasive because the scope of the linker recited in the amended claim 1 is still too broad: the length of the linker is undefined in claim 1 because the upper limit is not defined, n can be any integer that is greater than 1; the type of the linker encompasses any amino acids. The specification fails to provide sufficient guidance and working examples on how to make and/or use such a broad of genus of linkers and consequently fails to enable an artisan to make and/or use a compound comprising an undefined linker. In this regard, it is noted that, while PG5 shows an induction of cAMP in COS-7 cells expressing human PTH-1receptor, PG9, which has 4 more glycine residues in the

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linker, has a minimal effect on induction of cAMP (Fig. 3). Therefore, even the length of the linker can dramatically change the activity of the polypeptide, illustrating the unpredictability of the art.

Moreover, the specification discloses that the relative large size of native PTH or PTHrP presents challenges to the use of these peptides as treatment for osteoporosis and in general a protein of this size is not suitable for use as a drug (page 6, under summary of the invention). A high number of  $n$  in the formula  $S-(L)_n-B$  would yield a high molecular weight, which may be about or even higher than the molecular weight of native PTH or PTHrP.

Furthermore, since the specification does not provide a clear definition for the term "an amino terminal signaling function domain of PTH", independent claims 1 and 43 do not unambiguously define the "S" in the formula  $S-(L)_n-B$ . Therefore, one of skill in the art would not know how to make and use the invention.

Finally, it is noted that claims 10 and 11 recites, in part (b), "L is 5-10 glycine residues". In view of the instant disclosure, it appears that Applicants intend to recite "L is a glycine residue, and  $n$  is an integer from 5-10" in the claims.

#### **Claim Rejections Under 35 U. S. C. § 112, 2<sup>nd</sup> Paragraph**

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The rejection of claims 1, 2, 5, 6, 37, 41, and 42 under 35 U.S.C. §112, second paragraph, as set forth in Paper No. 04302004 (May 4, 2004), is maintained. Newly added claims 43 and 46 are also rejected on the same basis.

As noted in the previous office action, claims 1 and 43 recite "an amino terminal signaling functional domain of PTH", which is not defined in the specification unambiguously. Thus, it is not clear what the metes and bounds of the terms are, rendering the claim indefinite. Claims 2, 5, 6, 37, and 46 depend from claim 1, whereas claims 41 and 42 depend upon claim 43.

### **Claim Objection**

(i) Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It appears that the amended claim 1 now only reads on a polypeptide because recitation of use of an aliphaticdiamine as a linker molecule has been deleted from the claim. Thus, claim 2 does not further limit the subject matter of claim 1.

(ii) Claims 7-9, 14, 44, and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.



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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Brenda.Brumback@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li, Ph.D.  
Examiner  
November 18, 2004

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**